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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3731

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,085	Applicant(s) GELLMAN ET AL.	
	Examiner VICTOR X. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,9,11-18 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,9,11-18 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This Office Action is in response to communication filed on 3/1/2010.

Applicant amended claim 16 and added new claims 28-33.

Claims 1, 3-6, 8, 9, 11-18 and 28-33 remain pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8-9, 11-15, 17-18, 28, 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al US 5,607,389.

Claim 1: Edwards et al disclose a first placeholder element 312 insertable through tissue to a first selected location in a patient's body, the first placeholder element 312 including a first lumen extending there through to a distal opening which, when the first placeholder element is in the first selected location is adjacent to target tissue; a handle (the combination of items 276, 300) including a channel extending there through for receiving the first placeholder element 312, the channel directing elements inserted therein to the first lumen, the handle being removably (fig. 6) coupled to the first placeholder element so that the first placeholder element may be left in the first selected location; a tissue sampling element 6 insertable to the first selected location via the first lumen for obtaining a sample of tissue from the first selected location, the tissue sampling element being removable first lumen while leaving the first placeholder element 312 at

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the first selected location; and wherein a tissue treatment element 294 insertable to the first selected location via the first lumen.

Claims 3-4: Edwards et al disclose wherein the handle includes a sampling element actuator 10 for operating the tissue sampling element when the tissue sampling element has been inserted there through to the first lumen, and wherein the handle further comprises a sampling safety lock 12 which, when in a locked configuration, prevents actuation of the sampling element actuator.

Claims 5, 8, 12: Edwards et al disclose a second place holder element 318, a first luer 24 attachment for coupling the first placeholder element to the channel, and wherein the tissue sampling element comprises a second luer attachment 26 for coupling the tissue sampling element to the channel.

Claims 9, 11: Edwards et al disclose the sampling element comprises a biopsy needle (see col. 3, lines 50-67), and wherein the biopsy needle includes a suction lumen for applying suction to a sample of tissue for removal of the sample from the body (see col. 4, lines 30-40).

Claims 13-14: Edwards et al disclose the tissue sampling element further comprises an in-vivo tissue treatment device (see col. 8, lines 35-50), and wherein the tissue treatment element 294 is insertable through the first lumen of the first placeholder element when the first placeholder element 312 is separate from the handle 276,300.

Claims 15, 17-18: Edwards et al disclose the tissue treatment element comprises one of a monopolar and a bipolar electrode (see col. 9, lines 3-7), wherein the tissue treatment element 294 comprises a conduit for insertion of a chemical treatment substance to the first selected

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location. It is noted that the statement of intended use and other functional statements have been considered but are deemed not to impose any structural limitations on the claims distinguishable over Edwards reference which is capable of being used as claimed if one desires to do so; and wherein the tissue treatment element is coupleable to a source of electric power and employs the first placeholder element as an electrode (see col. 9, lines 3-7).

Claim 28: Edwards et al disclose the handle includes a fitting (combination of 314 and 316 is configured to be received in a corresponding shaped fitting on the tube 312) projecting distally therefrom configured to be received in a correspondingly shaped fitting in a proximal end of the first placeholder element.

Claim 30: Edwards et al disclose a first placeholder element 312 insertable through tissue to a first selected location in a patient's body, the first placeholder element 312 including a first lumen extending there through to a distal opening, which, when the first placeholder element is in the first selected location, is adjacent to target tissue; a handle (the combination of items 276, 300) including a channel extending there through for directing elements inserted into a proximal opening of the handle to the first lumen of the first placeholder element, the handle being removably (as best seen in fig. 6) coupled to the first placeholder element so that the first placeholder element may be left in the first selected location; a tissue sampling element 6 insertable through the proximal opening of the handle and the first lumen for obtaining a sample of tissue from the first selected location, the tissue sampling element being removable from the proximal opening of the handle while leaving the first placeholder element at the first selected location; and a tissue treatment element 294 is insertable to the first selected location through the first lumen.

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Claims 31-33: Edwards et al disclose wherein the handle includes a fitting (combination of 314 and 316 is configured to be received in a corresponding shaped fitting on the tube 312) extending proximally therefrom configured to releasably engage the tissue sampling element 6 wherein the handle includes a fitting extending distally therefrom configured to releasably engage the placeholder element; and wherein the tissue treatment element 294 is removably insertable through a proximal end of the placeholder element (fig. 6).

Claims 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al US 2001/0014779.

Claim 30: Burbank et al disclose a first placeholder element 102 insertable through tissue to a first selected location in a patient's body, the first placeholder element 102 including a first lumen extending there through to a distal opening, which, when the first placeholder element is in the first selected location, is adjacent to target tissue; a handle (202) including a channel extending there through for directing elements inserted into a proximal opening of the handle to the first lumen of the first placeholder element, the handle being removably (as best seen in fig. 1, paragraph 56, lines 3-6) coupled to the first placeholder element so that the first placeholder element may be left in the first selected location; a tissue sampling element 110 insertable through the proximal opening of the handle and the first lumen for obtaining a sample of tissue from the first selected location, the tissue sampling element 110 being removable from the proximal opening of the handle while leaving the first placeholder element at the first selected location; and a tissue treatment element 229 is insertable to the first selected location through the first lumen.

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Claims 31-33: Burbank et al disclose wherein the handle includes a fitting (210) extending proximally therefrom configured to releasably engage the tissue sampling element wherein the handle 202 includes a fitting extending distally therefrom configured to releasably engage the placeholder element; and wherein the tissue treatment element 229 is removably insertable through a proximal end of the placeholder element (fig.1).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al in view of Edwards et al US 6,692,490.

Burbank et al disclose the invention substantially as claimed (see fig. 1, col. 7, lines 65-col. 8, lines 31) except for the tissue treatment element includes an electrode which is a multi-barbed electrode. Edwards teaches the tissue treatment element includes an electrode which is a multi-barbed electrode (fig. 1, 119, see col. 5, lines 15-27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Burbank by constructing the device with the tissue treatment element includes an electrode which is a multi-barbed electrode as taught by Edwards in order to deliver the energy to the tissue and further to improve continence by improving the structural integrity of the tissue.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al in view of Milliman et al US 6,213,957.

Edwards et al disclose the invention substantially as claimed except for the placeholder elements comprise markings. Milliman teaches the placeholder elements comprise markings 601. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Edwards by constructing the device with markings as taught by Milliman in order to insert precisely and bring the working components of such minimally invasive instrument to precise location to conduct the desired procedure.

Response to Arguments

4. Applicant's arguments filed on 3/1/2010 have been considered but they are not persuasive. Applicants state that Edwards' 389 fails to suggest a handle is removably coupled to a first place holder element. Examiner disagrees. In fact, as seen in fig. 6, Edwards clearly shows that handle (the combination of 276 and 300 are removable or are separated and are coupled to the tube 312). There is nothing claimed which prohibits this interpretation of the prior art to be used as a handle can be removably coupled to the placeholder element. Accordingly, the above noted references are still considered to read on the claimed limitations of the claims noted.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTOR X. NGUYEN whose telephone number is (571)272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor X Nguyen/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/1/2010